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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,044	07/08/2003	Paul Andrew Benjes	223505	3936

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,044	<b>Applicant(s)</b> BENJES ET AL.	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 10/27/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1,8,9,11-17 and 19-23 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,8,9,11-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Art Unit: 1626

Claims 1, 8-9, 11-17, 19-23 are pending in this application.

Claims 2-7, 10, 18 are pending in this application.

***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/05 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 12-13, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims improperly depend from claim 11 for failure to limit the scope of claim 11. Steps (e), (f) and (g) are in the same sequential order in claims 11-13. By deleting claims 12-13 the rejection would be overcome.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-9, 11-17, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayakiri et al., Chem. Bull. Vol. 39, No. 6 (1991), pages 1392-1396, (Kayakiri et al., I) individually or in view of Kayakiri et al., Tetrahedron Let, Vol. 31, No. 2 (1990), pages 225-226 (Kayakiri et al., II), in view of Morrison et al., Org. Chem., 3<sup>rd</sup> edition, (1974), page 759.

Applicant claims a process of making kifunensine from compounds of formula I, and a process of making compounds of formula I comprising steps (a) to (d) set forth in claim 1, steps (e) to (i) set forth in claim 11 and steps (a) to (g) in claim 17. In preferred embodiment, applicant claims specific reagents and how the process is performed. In other embodiment, applicant changes the sequence of the reaction steps or combines steps/reagents from both prior arts – selective combination.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Kayakiri et al., teach a similar process of making kifunensine from compounds of formula I, and a process of making compounds of formula I. Kayakiri et al., teach all the instantly claimed steps, the reagents and reaction conditions. See pages 1392-1394, charts 1-7 and the experimental sections on pages 1394-1396 (first prior art) and pages 225-226 of second prior art.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

Art Unit: 1626

The difference between the instant invention and that of Kayakiri et al., is that applicant changes the sequential order of the reaction steps or combines steps/reagents from both prior arts - selective combination. Also, applicant now use N-acetyl protected D-mannosamine as the starting material instead of oxamoyl as N-protecting group by Kayakiri et al.

*Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)*

However, in a telephonic interview with the Examiner on/about 9/14/05, applicant admitted the sequence of the steps is not important and may vary. Selective combination of prior art(s) teaching is prima facie obvious. There is no indication of an interaction between the steps such that one of ordinary skill in the art would have any doubts that the selective combinations could not be made. *In re Mostovych*, 144 USPQ 38 (CCPA, 1964). Morrison et al., Org. Chem., 3<sup>rd</sup> edition, (1974), page 759, teach using acetate to protect N. See page 759, lines 1-2 4 of paragraph 7. Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to use N-acetyl protected D-mannosamine as the starting material instead of oxamoyl as N-protecting group at the time the invention was made. The motivation is from knowing that acetate is a N-protecting group.

Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive. In the claims applicant added N-acetyl as the protecting group at position 6, and contends that the prior art use N-oxamoyl protecting group. Applicant asserts that N-acetyl allows for a large-scale production. This is not persuasive because there is no support for this assertion in the specification, and using an analogous starting material in a well-known process is

Art Unit: 1626

prima facie obvious. *In re Durden*, 226 USPQ 359 (1985). In the instant N-acetyl and N-oxamoyl are analogous starting materials.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**

Group 1626

December 20, 2005